Exhibit H

United States v. Elizabeth Holmes & Ramesh Balwani, CR 18-258 EJD (N.D. Cal.),
Expert Report of Stephen Master, MD, PhD, FCAP, FAACC

March 6, 2020

I. Qualifications

I received my undergraduate degree in molecular biology from Princeton University and my MD and PhD (cell and molecular biology) from the University of Pennsylvania School of Medicine. I then did a residency in Clinical Pathology at the Hospital of the University of Pennsylvania, including time serving as Chief Resident in Clinical Pathology. After completing my residency, I spent a postdoctoral year as a research associate at Penn prior to joining the faculty as Assistant Professor of Pathology and Laboratory Medicine. During my time at Penn, I was appointed Medical Director of the Endocrinology Laboratory at the Hospital of the University of Pennsylvania, and I also spent 5 years as director of the University of Pennsylvania translational core laboratory. In 2015 I moved to Cornell as a faculty member at Weill Cornell Medical Center in New York City, where I was director of the Central Laboratory and Chief of Clinical Chemistry Laboratory Services at Weill Cornell Medicine / New York Presbyterian Hospital. In 2018 I returned to Philadelphia at the Children's Hospital of Philadelphia, where I currently serve as Chief of the Division of Laboratory Medicine, Medical Director of the Michael Palmieri Laboratory for Metabolic and Advanced Diagnostics, and Associate Professor of Pathology and Laboratory Medicine at the Perelman School of Medicine, University of Pennsylvania.

I am Board Certified by the American Board of Pathology (ABP) in Clinical Pathology, and I have additional subspecialty Board Certification from ABP in Clinical Informatics. I hold an active medical license in Pennsylvania. I am a Fellow of the College of American Pathologists as well as of the Academy of the American Association for Clinical Chemistry. I serve on the Board of Editors of the journal *Clinical Chemistry*, as well being an Associate Editor of *Clinical Proteomics* and Section Editor in Clinical Chemistry for the *Archives of Pathology and Laboratory Medicine*. I have been active professionally in the American Association for Clinical Chemistry, having served on their Board of Directors for five years. I serve as a member of the Harmonization Oversight Group of the International Council for the Harmonization of Clinical Laboratory Results. I currently have over 75 publications, including original research articles, reviews, and book chapters. In addition, I have lectured extensively at a national and international level on a variety of subjects related to Clinical Chemistry, including new paradigms for quality control. Of note, I was a member of the panel that facilitated questions and answers following the Theranos presentation at the 2016 annual meeting of the American Association for Clinical Chemistry.

My CV is attached as Appendix A.

II. Scope of Assignment

I have been retained by the United States Attorney's Office for the Northern District of California to testify as an expert witness in this matter. For purposes of this report, I was asked to provide opinions on whether Theranos was market ready and able to produce accurate and reliable fingerstick results for tests such as Vitamin D, chloride, potassium, bicarbonate, HIV,

HbA1c, hCG, cholesterol, and sodium, whether Theranos adhered to normal industry standards for clinical laboratory testing from 2013-2015, and whether any lack of adherence had the potential to adversely impact test accuracy and reliability. This report is intended to summarize my opinions and my anticipated testimony. I reserve the right to supplement or revise this report or to address additional questions if asked and based on additional information received and the evidence presented at trial. My compensation is $400 per hour. This report and the opinions contained herein are based on my training in clinical pathology and chemistry, my experience as a laboratory medical director, and my knowledge of standards and best practices as established by federal regulations and by the College of American Pathologists ("CAP"). I also considered publicly available information, scholarly research, and materials produced in discovery in this case, which are identified in Appendix B.

III. Background on Blood Testing

Blood Testing: Samples

Modern blood testing in the clinical laboratory begins with collection of a patient sample. Traditionally, this is performed using a needle that punctures a vein in the arm, and this process is called venipuncture. The blood that is collected from the vein in this way is called venous blood. A second way of collecting blood involves using a sharp lancet to puncture the end of a finger or (in the case of a newborn) the heel of a foot. The blood that is collected from these sources is known as capillary blood, because it comes from the very small blood vessels known as capillaries. In certain hospital settings, blood is collected from an artery ("arterial blood"). As oxygen-filled blood travels through arteries, then into capillaries, and

finally into veins for its return trip to the heart, tissues along the way can take up or secrete substances. As a result, there can be differences between arterial, capillary, and venous blood.

It is also worth noting that both arterial and venous blood samples are obtained using a needle inserted into a large enough blood vessel that there is very little concern about inadvertently collecting a significant amount of unwanted material. In the case of capillary blood, however, the fingerstick can, under some circumstances, break apart cells and/or release fluid that does not come directly from the blood vessel (capillary) itself. This may have more of an effect on some analytes than on others. For example, blood glucose testing from a fingerstick is widely accepted except in certain situations where a patient is not adequately delivering blood to their fingertips. Conversely, because the inside of a cell contains more potassium than the outside of a cell, breaking apart many cells could theoretically increase the amount of potassium in a sample (note that the same is true for any blood sample—arterial, venous, or capillary—if the red blood cells are broken apart; this is known as “hemolysis”).

Under normal circumstances, blood is removed from the body begins to clot. Given this issue, there are three primary ways that blood is handled for medical testing. The first method involves testing the blood before it has a chance to clot, and this whole-blood method is the basis of some portable (“point-of-care”) test devices such as glucose meters. In the second method, blood is drawn into a tube where it is allowed to clot, and then this collection tube is spun in a device known as a centrifuge. This spinning causes the clot itself to move to the bottom of the tube, and the remaining fluid, known as “serum”, can be used for testing. In the third method, the tube into which the blood is drawn contains what is known as an anticoagulant, which prevents clotting from taking place. There are several widely-used

anticoagulants, including heparin, EDTA, and citrate. When anticoagulated blood is spun in a centrifuge, the blood cells move to the bottom of the tube, and the remaining fluid is known as "plasma". Of note, different tests that are performed on may have different requirements in terms of the type of anticoagulant that is acceptable.

Once an appropriate sample has been obtained, blood can be tested in a variety of ways. A test for a given substance in the blood (or characteristic of the blood) is known as an "assay", and the substance being measured is known as the "analyte". So, for example, an assay for Vitamin D is a laboratory test where Vitamin D (the analyte) is measured in a sample. The instrument that performs the testing is considered a medical device, because it is used to diagnose a disease or other condition, and other components of blood testing, such as the tubes into which blood is drawn, are also considered medical devices. There are a variety of ways that testing is actually performed, such as monitoring a chemical reaction that produces a detectable change in light absorption, measuring the binding of an antibody to an analyte, or making copies of DNA or RNA such that a specific sequence can be detected. Most clinical laboratories utilize commercial instruments that accept a blood tube or smaller container, acquire up a small amount for testing, and return a result.

When the results of a blood test are reported, any quantitative result must include the "reference range" for that assay. This represents the expected normal range for the assay, and is determined by measuring results from a large group of healthy individuals. Upper and lower values of the normal range are set so that 95% of normal individuals fall in that range. Clinicians can use the reference range to determine if there is likely to be a significant abnormality in a patient's lab result.

Blood Testing: Assay Performance

There are two basic concepts that characterize the performance of a laboratory test: accuracy and precision. Accuracy refers to how close the result comes to the "true" amount of the analyte in a blood sample. That is, if a gold-standard reference assay measures that a patient has 30 ng/mL of Vitamin D in their plasma, then we would expect that an accurate laboratory assay should also return a result that is close to 30 ng/mL. If the typical result from a given assay returns 28 ng/mL, we say that this assay is exhibiting "bias". A certain amount of bias is a normal and expected feature of laboratory tests; however, the degree of bias that is allowed depends on a number of issues, including the clinical implications for the patient.

Precision refers to the degree to which a laboratory test gives the same result when it measures an identical sample many times. As with accuracy/bias, all laboratory tests have a certain amount of inherent imprecision. To use one analogy from outside the laboratory, when a patient has their temperature measured, we understand that there is some variability. One time it read 98.6˚F, and if it is remeasured immediately it might be 98.7, 98.5, or some other value that is close to the "true" temperature. This does not mean that the patient's temperature is actually changing; it simply may reflect slight variations in measurement. Similarly, laboratory tests will differ from measurement to measurement, simply due to random chance. The amount that a test can change from run to run when measuring the same sample over and over can be expressed as the "percent coefficient of variation" (%CV). If a test has a 5% CV, then most of the time (68% of the time) the measured value will be between 5% of the expected value. For example, if the expected value of the test is 100, then most of the time the

measured value will be between 95 and 105 (this is equivalent to saying that it will be within 1 SD at this expected value). Less frequently (27% of the time) it may be further away than 95-105, but still between 90 and 110. However, 95% of the time it will be between 90 and 110. Because the imprecision of the test influences its interpretation, it is important that this variation be carefully controlled and understood. Typically, for a quantitative analyte in the clinical lab, the maximum imprecision at which a value would be reported is 20%CV, and it is much more common to have imprecision that is significantly less than 10%.

Accuracy and precision are linked, because the most important question is whether a lab test can accurately guide patient care. The concept of total allowable error (TEa) captures this by asking how close to the "true" value a lab measurement can be while still being appropriate for clinical use. The total error in a measurement is a combination of the bias and imprecision. Even an assay with no bias can be unacceptable if the imprecision is too high. Similarly, an assay that is perfectly precise, but which has excessive bias, will give an answer that is medically misleading. To fit within the TEa, the more bias an assay has, the more precise it has to be; the more imprecise it is, the less bias it can tolerate. If an assay is shown in practice to have excessive bias or imprecision, it is not suitable for clinical use.

Another fundamental factor that affects lab performance is the presence of interferences, including hemolysis (a breaking apart of the red blood cells that releases hemoglobin), icterus (interference from a substance known as bilirubin), and lipemia (excessive fat in the blood). Because these interferences can significantly affect the laboratory value, it is important the degree to which each assay is affected, as well as to develop a mechanism to detect the presence of these interferences in a patient sample.

Blood Testing: Regulation

In the US, clinical testing is regulated by the Clinical Laboratory Improvements Amendments (CLIA), which specifies the legal requirements for engaging in medical testing and is broadly administered under the Center for Medicare and Medicaid Services (CMS). Labs that wish to do testing must acquire a CLIA certificate, and the type of CLIA certificate they obtain determines the type of testing that they are allowed to perform. Laboratories that engage in medium- or high-complexity testing must not only obtain the appropriate type of certificate, but are also subjected to regular inspections by the state / CMS or by a team sent from an approved accrediting agency.

The US Food and Drug Administration (FDA) classifies the degree of complexity (for example, medium- or high-complexity) associated with laboratory tests that they have approved or cleared. These classifications not only determine which laboratories can run the tests, but also specify the personnel requirements to run or oversee the tests. Tests become FDA-approved or cleared through a formal approval process that involves submission of specific types of data demonstrating important characteristics of the test, such as accuracy, precision, and the range of values over which the test gives valid results. FDA approval or clearance allows a manufacturer to legally sell the test to others, and CLIA specifies that a lab running an FDA-approved test must first verify the performance of the test in their own laboratory to ensure that it matches the specifications.

Although the majority of tests in most laboratories are FDA-approved or cleared assays, there is a provision under CLIA for laboratories to develop their own in-house tests, known as

lab-developed tests (LDTs). LDTs are automatically classified as high-complexity tests, and thus no LDTs could ever be legally run in a laboratory that was only certified for medium-complexity testing. LDTs can, of course, be an entirely new test that is created by a high-complexity laboratory; however, any alteration to an FDA-approved or cleared test (such as a new sample type) makes that test into an LDT. In my experience, a disclaimer is always added to LDT results indicating that the test is not FDA approved or cleared, but has been validated by the laboratory.

One practical significance of LDT classification is that CLIA requires additional experiments in order to determine that an LDT is suitable for clinical use. Rather than simply verifying existing performance specifications as with an FDA-approved test, an LDT requires validation not only of accuracy, precision, and reportable range, but also of interferences and other factors. Additionally, the reference range must be established, which typically takes many more samples than would be required to simply verify a reference range that had previously been approved by the FDA. As a benchmark, while verification of an established, FDA-approved reference range can be performed with 20 samples, it is typical to use 120 samples to establish a new reference range for an LDT.

A second major requirement of CLIA is a designated laboratory director, who is legally and medically responsible for results that are returned from the laboratory. The director is ultimately responsible for all aspects of testing, including the analytical portions as well as reporting of results. Because the laboratory director is ultimately responsible for determining that the results are appropriate for medical use, it is critical that they be given appropriate authority to ensure that staffing, processes, instrumentation, and other resources are

sufficient. Further, for a high-complexity laboratory that is developing LDTs, the operation of those LDTs and their maintenance is the responsibility of the laboratory director.

A third requirement of CLIA is that laboratories engage in proficiency testing (PT). Proficiency testing is intended to ensure that different labs return values that match each other to a significant degree. Typically, identical samples are sent to multiple laboratories, and they are each required to run that sample exactly as they would a patient sample. PT results are then sent back to be graded and compared to the results from other laboratories. If the lab returns values that are similar to what other labs have reported, they have passed their proficiency testing for that analyte. For a set of common analytes, CLIA mandates that the lab enroll in an accredited PT program. Under certain (relatively rare) circumstances where PT is not available for a given analyte, it may be appropriate to document alternative ways of assessing PT using patient samples that are exchanged between laboratories or to compare patient samples to an existing assay for the same analyte.

In addition to proficiency testing, which occurs only a few times a year, CLIA also mandates that a lab perform a quality control check at various intervals (daily, or even more often). Quality control (QC) is intended to ensure that the equipment and assay process are functioning appropriately, and that nothing has changed that would affect patient results. Typically, the lab has a standard set of quality control materials for each assay, and these cover the important ranges that may be seen in patient samples (for example, one quality control sample at the low end of the measurement range, and one at the high end). When the assay is established, the lab establishes an acceptable range for the quality control. If a quality control specimen is too far away from this acceptable range, specified rules are applied to determine if

the assay is "out of control". An assay that fails quality control requires some sort of intervention, whether that is recalibration of the assay, or something more significant. If an assay is found to be out of control after continuously running samples, the lab would need to determine whether the issues with the assay affected patient results that should be corrected or cancelled.

IV. Summary of Opinions

Preliminary comments

Based on the documents that I reviewed, my understanding is that there were two primary methods that Theranos employed to measure analytes from fingerstick blood samples collected in small devices ("CTNs"). First, they had developed an instrument (often referred to as "Edison", version 3.5) that performed immunoassays. Second, they used Tecan liquid handlers to dilute small samples and run them on traditional clinical chemistry analyzers obtained from other vendors (predominantly Siemens Diagnostics). Because neither of these approaches used unmodified, FDA-cleared or approved assays in an unmodified form, they are both considered laboratory-developed tests (note that I am not here taking a position on the FDA's role in regulating these laboratory-developed test, simply pointing out their classification under CLIA). There is a third class of testing that Theranos was performing using traditional venous samples on FDA-approved or cleared instruments from third-party vendors. I will not make many comments about this last class of testing, since it is identical to the testing performed in most labs in the U.S.

Related to this discussion, it is my opinion that, when considering the two Theranos methods for testing fingerstick samples, only the first method employing an Edison-style (or, later in 2016, miniLab-style) instrument could ever, under any conceivable future model, have been developed into an instrument that could be deployed at a remote site in closer proximity to the patient (i.e. not at a central reference lab site).

Assessment of Theranos blood testing technology

In my opinion, Theranos was not market ready and able to produce accurate and reliable fingerstick results for tests such as Vitamin D, chloride, potassium, bicarbonate, cholesterol, and sodium. In addition, there are substantial questions about the ability of their laboratory to provide patient-appropriate results for calcium, HIV, HbA1c, and hCG. In the following section, I will provide some of the primary reasons and evidence that support this opinion.

In order to produce accurate and reliable results, a clinical assay must typically agree with the accepted results from a gold standard (accuracy), and it also must be able to do this reproducibly (reliable). This reproducibility is referred to as precision, the imprecision of an assay can be measured as %CV. As a benchmark, for example, a 2010 publication testing a commercially-available vitamin D assay showed a %CV of roughly 12-18%. Theranos had a standard operating procedure protocol that indicated that validated assays must have 15%CV, with a possibility of 20%CV at the extremes of the assay. However, the report of the CMS inspection from 2015 shows that, in the course of routine operations, Theranos QC measurements for this assay on a single instrument demonstrated a CV as high as 63.8%. This

was not limited to a single instrument; of the other two instruments documented in the CMS report, one showed a CV of 31.9%, and the other still exceeded the written Theranos standard. This suggests a broader problem with Theranos manufacturing and maintenance, whether at the level of the Edison itself or of the reagent/consumable production. This problem was not confined to a single assay: the CMS report documents similar issues with assays for Vitamin B12 and SHBG (sex hormone binding globulin), which were also run on the Edison. The precision issues with Vitamin B12 were documented on 5 different instruments, further supporting the opinion that this was a widespread issue rather than a single "bad" instrument or assay. An internal Theranos email from 2014 reports that 26% of QC runs failed across 7 assays running on the Edison platform. Theranos themselves subsequently (and appropriately) voided all tests performed on this platform, effectively acknowledging that the results were not sufficiently accurate and reproducible for patient care.

The CMS QC data also demonstrates problems with the accuracy of Edison assays that were in operational use for patient samples. The CMS report documents a Vitamin D instrument assay that delivered QC results >2SD from the target mean for 15 days in a row, suggesting a bias in the instrument. It is not possible to be certain whether this was due to inherent issues with the technology, or with poor lab operational practice (although both cases can adversely affected the quality of the clinical laboratory results). However, the same phenomenon is seen in multiple other instruments running multiple other assays, showing at a minimum that the accuracy of the instruments was not consistent. Furthermore, testimony from the laboratory director (Adam Rosendorff) indicated that it would be lab policy to recalibrate an instrument that was failing QC, and we know from other testimony of an

example when QC was persistently out of control to the extent that points were removed from the calculation in bring the QC numbers into conformity. For these reasons, it is reasonable to conclude that the instrument problems were not merely a result of poor operational practice, but were related to the quality of the instruments and assays themselves.

Precision and accuracy issues also affected fingerstick assays that were diluted on the Tecan liquid handler and measured on modified third-party instruments. For example, a published report from a group at the Icahn School of Medicine demonstrated a significant negative bias in the measurement of cholesterol by Theranos compared with both Quest and LabCorp. Although it is clearly the case for many analytes that there are issues of standardization and harmonization between assays used by various clinical laboratories, this amount of difference in cholesterol levels was beyond what would be expected given the standards of the field. Additionally, inaccuracies in a lipid testing result were brought to the attention of the laboratory director in late 2014, who noted that they were inconsistent with commonly-utilized estimates of the relationship between the various components of the lipid test (such as cholesterol). These strands of evidence support the idea that there were significant accuracy limitations to the Theranos fingerstick cholesterol test.

In April 2014, potassium fingerstick measurements were shown to be abnormally high 17% of the time. In a healthy population, one would expect to see ~2.5% abnormally high values, and even accounting for prevalence of illness the percentage of high values indicates a fundamental issue with the assay as it was being performed. There are at least two possible explanations for this: the Theranos assay had significant positive bias (i.e. was inaccurate), or the fingerstick collection modality, possibly including the CTN, led to high hemolysis rates which

artifactually elevated the potassium. If the latter was the case, the laboratory clearly did not have a robust method of detecting these hemolyzed samples prior to testing. In either case, Theranos was not providing an accurate potassium test during this time frame.

Other electrolyte measurements (e.g. sodium, chloride) were the subject of “frequent complaints” from customers according to internal Theranos emails. In an email dated October 27, 2014 from the laboratory director (Adam Rosendorff) to Sunny Balwani and Elizabeth Holmes, Dr. Rosendorff indicates that the laboratory had instituted a policy of canceling significantly high or low sodium values because “…we have no way of knowing for sure whether the result is truly abnormal or artifactual to the assay, or related to a specimen integrity issue.”

More generally, there are inherent limitations to the approach that Theranos had taken for small-volume testing using diluted specimens compared with the original assays. Because a less concentrated specimen is more difficult to detect at low levels, both the precision and lower limit of detection would be expected to be inferior. While there might be technical solutions to ameliorate this problem, Theranos’ own internal documents discuss degradation of precision due to a variety of factors in their process, as well as plans to decrease the amount of dilution in order to improve performance.

Based on customer complaints and Theranos internal investigations, there were significant issues with calcium, HIV, HbA1c, and hCG assays during the time that these were performed on fingerstick samples. In some cases, there are insufficient additional details in the material I have reviewed to determine the cause of these issues, the relationship to either the sample type or Theranos technology, or the resolution of the problems. HbA1c issues appear to be due to organizational problems with tests being done on different platforms, and

Theranos' practice of not reporting whether the result was obtained from fingerstick or venous blood exacerbated the confusion. In the case of hCG, multiple inaccurate results had significant and negative clinical implications for patients. Although in many cases I have not been able to identify a clear paper trail demonstrating the root cause of these inaccuracies, it is noteworthy that HIV, HbA1c, and hCG do not appear on the list of LDTs provided to the FDA by Theranos on 8/26/2015, and thus they had not been found to be suitable for continued clinical use by that point.

As mentioned above, the testimony of Adam Rosendorff indicates that Theranos did not adequately distinguish on reports whether a reported value came from a fingerstick or venous sample, and the reference ranges were not all appropriately adjusted to account for fingersticks. This is evident in an examination of the primary documents. For example, in the Theranos validation document for chloride, the same reference range was used for venous and fingerstick. However, visual inspection shows a clear positive bias in the fingerstick samples. By obscuring the nature of the sample and not providing an adjusted reference range, a clinician or patient would be unable to distinguish a true change vs. a difference that is due to the differing nature of venous and capillary blood and/or the assay.

Internal emails and documentation show that Theranos were struggling with a number of ongoing technical issues involving hemolysis, sample leakage, variations in materials that affected function, and other issues with the CTN. This is consistent with the issues surrounding potassium (see above). An internal company email from 2016 refers to fundamental design issues in the EDTA-containing collection device that cause hemolysis.

In 2016, in a public session at the Annual Meeting of the American Association for Clinical Chemistry, Theranos publicly announced an additional instrument (the "miniLab") that they had not previously used in clinical testing through 2013-2015. Although some performance data were shown for a small number of assays, there were no clear data on the robustness of the machines in an operational setting, which would raise concerns based on the fact that previous Edison instruments that had reportedly passed validation were nonetheless shown by the QC performance to not yield reproducibly accurate, reliable results. During the presentation, Theranos also acknowledged that what they showed was not ready for patient testing.

Assessment of Theranos laboratory performance relative to industry standards

In my opinion, Theranos did not adhere to normal industry standards for clinical laboratory testing from 2013-2015. Further, this lack of adherence had the potential to adversely impact test accuracy and reliability.

In documented cases, it was noted that the Theranos QC system for Edison devices did not prevent samples from being run when the QC was out of the appropriate specifications. On pp. 37-41 of the CMS report, the inspectors documented a large number of instances where the QC system designed to prevent running samples on an out-of-control instrument did not function. Running patient samples when QC is giving values out of the acceptable range directly impacts the accuracy and reliability of the results that are returned to the patient or clinician.

Theranos did not appropriately engage in proficiency testing. From the testimony of the lab director at the time, Adam Rosendorff, proficiency testing was only performed using unmodified third-party, FDA-approved platforms. Proficiency testing for Theranos-modified third-party platforms and for the Edison was not performed, even when the Theranos-modified test became the primary test for the laboratory. Additionally, Theranos developed an internal rationale for utilize so-called alternative proficiency testing. In my opinion, it is not consistent with the standards of the field for a laboratory to unilaterally decide that they should be exempt from properly participating in PT for a listed CLIA analyte. There are clear examples where a sufficient peer group does not exist for a method, and the authorized PT provider simply groups the results with others running the same analyte on a different platform. In my opinion, the burden of proof would be on the laboratory to demonstrate to the PT provider that a significant commutability issue exists for their method. Even granting Theranos' interpretation, however, alternative proficiency testing was not appropriately performed (to the laboratory director's knowledge) at any point prior to October 2014, and thus Theranos was not appropriately ensuring the ongoing accuracy of their assays. The CMS report makes a similar point (not with PT *per se*, but with instrument-to-instrument comparison) for individual Edison analyzers. Theranos did not adhere to industry standards, and this had the potential to adversely affect the accuracy of their results. Additionally, if and when Theranos reported results of proficiency testing, those results were not derived from Theranos technology.

As recently as Fall 2015, Theranos did not have FDA approval or clearance for their CTN. This is significant, because (as described above) internal emails and documentation show that they were struggling with a number of ongoing technical issues involving hemolysis, sample

leakage, variations in materials that affected function, and other issues. These issues in and of themselves could affect the accuracy and reliability of their results. Further, however, from a regulatory perspective Theranos argued that their collection device, which was used in settings far removed from their high-complexity laboratory, fell under the umbrella of their laboratory-developed test. In my experience, I am unaware of any laboratory that has similarly attempted to extend the boundaries of their lab-developed test in this way. Thus, it is my opinion that this is not in accordance with normal industry standards, and, based on the reported issues, the lack of demonstrating performance data sufficient to obtain FDA clearance for use of this device had the potential to negatively impact their test results.

Finally, as stated in the section on the regulation of blood testing, in my experience a disclaimer is always added to LDT results indicating that the test is not FDA approved or cleared, but has been validated by the laboratory. There was no indication on the report to a clinician that would indicate that a given test was not FDA approved or cleared, or would allow a clinician to distinguish in any way between tests that Theranos was performing by their own methods and tests that Theranos was performing using traditional, approved third-party analyzers. The lab director, Adam Rosendorff, who is responsible for the reporting of results, raised this issue; however, he was told by Mr. Balwani that such a disclaimer was not required.